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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,726	11/25/2005	Heinz Von Der Kammer	37998-237386	3700
26694	7590	12/19/2007	EXAMINER	
VENABLE LLP			CHERNYSHEV, OLGA N	
P.O. BOX 34385			ART UNIT	
WASHINGTON, DC 20043-9998			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/525,726		VON DER KAMMER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Olga N. Chernyshev		1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 9-15, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

1. Claims 8 and 17 have been amended as requested in the amendment filed on October 16, 2007. Following the amendment, claims 1-19 are pending in the instant application.

Claims 1-7, 9-15 and 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 18, 2007.

Claims 8, 16 and 17 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on October 16, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### *Specification*

4. The text of the instant specification, including claims, remains not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03), see reasons of record in section 5 of Paper mailed on July 16, 2007. Appropriate correction is required.

### *Claim Rejections - 35 USC § 101*

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 8, 16 and 17 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 7 of Paper mailed on July 16, 2007. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological significance of the binding of this protein to a specific physiological function or a clinical condition.

Applicant traverses the rejection on the premise that "Figure 3 shows the differential expression of the foap-13 gene in AD patients versus healthy controls. This test, using RT-PCR, indicates that persons with AD exhibit differential expression of foap-13 in the temporal cortex relative to the frontal cortex" (p. 11 of the Response). Applicant further submits that "[t]he pending claims, as amended, are directed to assays for testing compounds to determine the degree of binding of the compounds to the protein in SEQ ID NO: 2 (foap-13). These assays have at least the specific and credible use of being used to detect the disclosed marker (foap-13 expression) to determine whether a patient has AD or other neurodegenerative disease". Applicant's arguments have been given careful consideration but are not persuasive for the following reasons.

The instant claims are drawn to an assay for testing compounds for the degree of binding of compounds to the protein of SEQ ID NO: 2 (foap-13 protein). The protein of SEQ ID NO: 2 is not novel, it has been identified within at least two separate publications: WO200112662 document (reference FP2 of IDS submitted on 09/30/2005) lists the protein as a "membrane associated protein MEMAP-12) and WO200153312 document (reference FP4 of IDS of 09/30/2005) lists the protein as a hypothetical protein. As fully explained in the previous office

action of record, the biological function of foap-13 protein of SEQ ID NO: 2 is currently unknown or not disclosed. The specification fails to present any evidence that foap-13 polypeptide of SEQ ID NO: 2 plays any specific physiological role in the etiology of Alzheimer's disease or any neurodegenerative process in general. This alone is not probative of lack of utility under 35 U.S.C. § 101, but is merely one of the analyses, which must be made. While not required by any statute or rule, if Applicant had disclosed a biological role or function of the foap-13 polypeptides, such might support a disclosed utility, such as for diagnosis or treatment of disease. In the instant case, the factual information presented in the disclosure is limited to differential expression of the protein, foap-13 of SEQ ID NO: 2, in different areas of AD brain as compared to normal control. The data are presented as ratio, see Table 1, for example. However, the instant claims are directed to assays to test the binding capability of the protein of SEQ ID NO: 2. The specification discloses finding of differential expression of foap-13 protein in brain tissue of patients with AD but discloses no utilities based on detection of binding between a compound and the foap-13 protein of SEQ ID NO: 2, as currently claimed. In the absence of knowledge of the biological significance of finding a degree of binding capability of this specific foap-13 protein and the relevance of measuring this particular parameter to AD diagnosis, there appears to be no immediately obvious patentable use for the instant claimed invention. For example, if the worker of skill in the art identified "the degree of binding", see the final step of claim 8, would that mean with respect to diagnosis of Alzheimer's? Since the instant claims fail to recite any steps related to an individual suffering from AD (obtaining samples, analyzing pattern of distribution etc.), the claims, as currently presented, are limited only to assessment of binding between random compounds and the protein of SEQ ID NO: 2. The

Examiner maintains that in the absence of knowledge of significance of this process of binding, the instant assay clearly encompasses using protein of SEQ ID NO: 2 as the object of further research, which is prohibited by the Supreme Court decision of *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966). The *Brenner* Court held that “[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” *Id.* at 534-35, 148 USPQ at 695.

Thus, for reasons of record fully explained earlier and reasons above, the instant rejection is maintained.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8, 16 and 17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Conclusion***

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/525,726  
Art Unit: 1649

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

December 10, 2007